

CLAIMS

1. Coated particles based on granulated microcrystals of ibuprofen, its isomers and its pharmaceutically acceptable salts, characterized in that they have a coating consisting of a mixture comprising
- 5 A) from 5 to 50% by weight, preferably from 10 to 30% by weight, of ethyl cellulose, based on the ibuprofen,
- B) from 10 to 60% by weight, preferably from 15 to 50% by weight, of hydroxypropyl methyl cellulose, based on the ethyl cellulose, and
- 10 C) from 0.1 to 40% by weight, preferably from 3 to 25% by weight, of silica with antistatic and permeabilizing properties, based on the ethyl cellulose,
- said coating - of which at least one of the constituents can be used for the granulation of the ibuprofen microcrystals to produce said particles - masking the unpleasant taste of the ibuprofen, significantly reducing its irritant effect on the
- 15 throat after swallowing, and releasing the ibuprofen substantially immediately when the particles are placed in an aqueous medium.
2. Particles according to Claim 1, characterized in that the silica with antistatic and permeabilizing properties (C) is precipitated silica.
3. Particles according to one of Claims 1 or 2, characterized in that they also
- 20 contain an agent (D) favouring the solubilization of the ibuprofen, said agent being selected from the group comprising mannitol, starch, pharmaceutically acceptable self-emulsifying bases, polyvinylpyrrolidones, stearic macrogol glycerides, alkali metal salts of organic origin, surfactants and mixtures thereof, it also being possible for said agent (D) to be used for the granulation of the crystalline ibuprofen.
- 25 4. Particles according to one of Claims 1 to 3, characterized in that the size distribution of the particles is such that at least 80% of the particles are between 100 and 500 μm and less than 15% of the particles are smaller than 100 μm .
5. Particles according to one of Claims 1 to 4, characterized in that, in a buffer solution of pH 7.2, 80% of the ibuprofen is released in 30 minutes and preferably in
- 30 15 minutes.
6. Process for the preparation of coated particles based on granulated microcrystals of ibuprofen, its isomers and its pharmaceutically acceptable salts, characterized in that it comprises, simultaneously or successively, phases consisting in granulating the ibuprofen microcrystals and coating them with a mixture

205060 "TOT" 030502

comprising

A) 5 to 50% by weight, preferably 10 to 30% by weight, of ethyl cellulose, based on the ibuprofen,

5 B) 10 to 60% by weight, preferably 15 to 50% by weight, of hydroxypropyl methyl cellulose, based on the ethyl cellulose, and

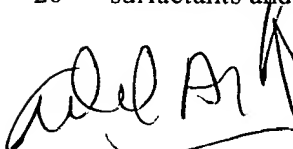
C) 0.1 to 40% by weight, preferably 3 to 25% by weight, of silica with antistatic and permeabilizing properties, based on the ethyl cellulose;

at least one of the constituents of the mixture used for the coating can be used for the granulation of the ibuprofen microcrystals.

10 7. Process according to Claim 6, characterized in that the granulation and coating phases take place simultaneously.

8. Process according to Claim 6 or 7, characterized in that it is carried out in a fluidized bed apparatus with an aqueous-alcoholic dispersion under conditions such that the temperature of the ibuprofen is always below 45°C, preferably below 30°C.

15 9. Process according to one of Claims 6 to 8, characterized in that, in the granulation and/or coating phases, an agent (D) favouring the solubilization of the ibuprofen is also used, said agent being selected from the group comprising mannitol, starch, pharmaceutically acceptable self-emulsifying bases, polyvinylpyrrolidones, stearic macrogol glycerides, alkali metal salts of organic origin,
20 surfactants and mixtures thereof.



205000 "T0T0E850